

Parametrix

5808 LAKE WASHINGTON BLVD. NE, SUITE 200
KIRKLAND, WASHINGTON 98033-7350
T. 425.822.8880 F. 425.889.8808
www.parametrix.com

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Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
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Washington, DC, 20460

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RE: TSCA 8(e) Submission



Dear Sir/Madam:

Parametrix, Inc. is submitting preliminary results from a combined oral repeated dose toxicity study with reproduction/developmental toxicity screening in rats to the United States Environmental Protection Agency (USEPA) pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA). The study provides information on chlorotrioctylstannane CAS # 2587-76-0.

Parametrix, Inc. is making this submission on behalf of the Organotin Environmental Programme (ORTEP) Association Member companies producing chlorotrioctylstannane in the United States. The managing parties of this international consortium assert on behalf of the sponsoring companies that this notice does not involve effects in humans. It does not contain confidential business information [CBI] under TSCA.

Information below is based on the audited draft report of a study conducted in accordance with OECD guideline 422.

Groups of 12 male and 12 female rats were administered test substance mixed in feed at 0, 300, 750, and 4000 mg/kg of diet. During the intervals measured, test substance intake of the male animals ranged from 20-21, 49-51, and 240-248 mg/kg body weight/day while the ranges in females were 17-26, 41-62, and 170-242 mg/kg body weight/day for the low, mid, and high dose, respectively.

Mean body weights and body weight changes were statistically significantly decreased in the high dose males and females at most measurement intervals.

Reduced relative and absolute thymus weight, lymphoid depletion of the thymus, and very slight to slight paracortical lymphoid depletion were reported in some high dose males and females and one mid dose female. Reductions in thymus weight in the mid dose group did not reach statistical significance.

Food consumption was also consistently decreased in the high dose males and females, and at one time interval in the mid dose females.

Statistically and/or biologically significant reproductive findings in the high dose group included:

- Prolonged precoital time and duration of gestation
- Reduced gestation index
- Increased postimplantation loss
- Lower number of dams with liveborn pups
- Increased number of stillborn pups and dams with all stillborn pups
- Reduced numbers of pups per litter and of liveborn pups per litter
- Increased postnatal pup mortality
- Lower sex ratio (lower number of male pups) on PN day 1
- Lower mean pup weights and increased numbers of runts

At the mid dose there was a statistically significant decreased number of liveborn pups per litter.

The no observed adverse effect level (NOAEL) for general and reproductive toxicity is 300 mg/kg of diet in this study.

Further questions regarding this submission may be directed to me at (425) 822-8880. Final reports are available to the Office of Pollution Prevention and Toxics upon request.

Best regards,
PARAMETRIX, INC.



Terry Phipps
ORTEP Association
High Production Volume Technical Coordinator

cc to Managing Parties:

- ATOFINA Chemicals, Inc.
- Crompton Corporation
- Rohm and Haas Company

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5808 LAKE WASHINGTON BLVD NE
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